Digital patient engagement/patient centric technologies

Aly Talen
Disclosure

Speaker name:

Aly Talen

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

✓ I do not have any potential conflict of interest
Trends affecting clinical research

1. Information is widely available

2. Technology is used by an increasing population
1. Information

The internet is full of information about our diseases.

Selection of relevant information is often hard.
2. Technology
Technology adoption

Annual Growth
Year-on-year change in key statistical indicators

- Internet users: +10% since Jan 2016, +354 million
- Active social media users: +21% since Jan 2016, +482 million
- Unique mobile users: +5% since Feb 2016, +222 million
- Active mobile social users: +30% since Jan 2016, +581 million
Technology adoption

Smartphone adoption among seniors has nearly quadrupled in the last five years
% of U.S. adults who say they have or use the following

Internet
Home broadband
Smartphone
Tablet
Social media

Source: Survey conducted Sept. 29-Nov. 6, 2016. Trend data are from previous Pew Research Center surveys. "Tech Adoption Climbs Among Older Adults"

PEW RESEARCH CENTER
Clinical Research – Data

Connecting the dots...
Clinical Research – Data

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2017
EMA/15975/2016
Good Clinical Practice Inspectors Working Group (GCP IWG)

Guideline on GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials
Clinical Research - Patient

Giving control to the patient
Clinical Research - Monitoring

Increased continuous measuring
Swedish nuclear physicist just got the world’s first approved birth control app - as effective as the pill but using only mathematics.
Birth control app reported to Swedish officials after 37 unwanted pregnancies

Users of Natural Cycles, first app certified as contraceptive method in Europe, identified among people seeking abortions at hospital

Julia Carrie Wong

Wed 17 Jan 2018 21.42 GMT
Clinical Research – eConsent

Improving
- Usage of other tools (video’s, interactive)
- Version control
### Recent additions / changes

<table>
<thead>
<tr>
<th>Date</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 17, 2017</td>
<td>New document (v1.0, 10.12.2017): Guideline on the retention period of biological material and personal data of further use projects without the informed consent of the persons concerned (according to Art. 34 HRA) (in German): <a href="#">pdf</a></td>
</tr>
<tr>
<td>December 11, 2017</td>
<td>New document (1.0): Guideline on the use of electronic informed consent (eIC) in clinical trials: [docx], [pdf]</td>
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Clinical research - Management
Clinical research - Management

**Enrollment Status**
- Enrollment: 101
- Active Sites: 34
- Enrolling Sites: 33
- Enrolled vs Target: 101 vs 750
- AE & SAE: 13
- PD: 75

**Patient Visit Status**
- Visits for Discharge by Site
- Cumulative Patient Enrolled per Month

**Safety Status**
- SAE & AE by Site
- AE Type

**CIP Deviation Status**
- PD by Site
- PD by FU point

**Study Sites**
- Center ID
- Center Name

**Follow up Visit Status**
- Count of Visit:
  - 1 Month Follow-up: 68
  - 6 Month Follow-up: 7
  - 9 Month Follow-up: 1

**Patient Screening by Site**
- Screen failure
- Screened

**Randomization Group**
- 34 (33.66%)
- 67 (86.34%)

**CEC reportable Events**
- 1 Month Follow-up
- Average PD per Patient by Site
Patient centric healthcare
Digital patient engagement/patient centric technologies

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